OBJECTIVES: To highlight the importance and impact of imputation approach used in reporting rheumatoid arthritis (RA) clinical trial results when data are analyzed using non-responder imputation (NRI) versus last observation carried forward (LOCF). METHODS: Non-responder imputation is a conservative analysis method in which participant dropouts are assumed to be non-responders regardless of actual response status at the time of dropout. Last observation carried forward is an analysis method in which the last measured value of a variable, such as treatment response, is carried forward and assumed to be valid for a future point of analysis if the participant drops from the trial, a double-blind, randomized trial in adult patients with early RA (<3 years) that compared among adalimumab plus methylprednisolone (ADA+MTX) and monotherapies with either drug were compared using NRI and LOCF analyses. Outcome measures presented here are American College of Rheumatology (ACR) 50%, and 70% responses, and remission based on 28-joint Disease Activity Score (DAS28<2.6). RESULTS: In the ADA+MTX treatment group, outcome measures calculated using NRI and LOCF, respectively, were 62% and 68% for ACR50, 46% and 48% for ACR70, and 43% and 47% for remission. In the MTX group, NRI and LOCF, respectively, were 46% and 49% for ACR50, 28% and 29% for ACR70, and 21% and 22% for DAS28<2.6. For all outcome measures, the estimate of drug effect was lower when using NRI analysis compared with LOCF analysis. CONCLUSIONS: Non-responder imputation analyses tend to result in more conservative estimates of drug effect on outcome measures as compared with LOCF analysis. In trials in which a high number of participant dropouts, the difference in results using NRI versus LOCF could be substantial. Thus, caution is warranted in comparisons of results across clinical trials using these different imputation methods.

OBJECTIVES: To compare the two risk adjustment models when estimating health care costs of rheumatoid arthritis patients. METHODS: Continuously eligible adult patients with confirmed diagnoses of RA between June 2004 and June 2009 were included. Patients were new to tumor necrosis factor (TNF) therapy and subsequently either switched to another anti-TNF or escalated their dose. The difference in total health care costs and RA-related health care costs between switchers and escalators 1 year after the switch/escalation was estimated using the propensity score matching and instrumental variable methods. When using propensity score matching, the differences in patient, clinical, cost, and utilization characteristics during the baseline period were controlled. When using the instrumental variable method, patients’ copayment, distance from patient to provider, and doctors’ prescribing patterns were used as instruments to estimate the outcomes, while controlling for differences in patient and clinical characteristics were controlled as well. RESULTS: After risk adjustment using propensity score matching, the difference between switchers and escalators is €64 in total healthcare costs, and €245 in RA-related health care costs. After using the instrumental variable method, the difference between switchers and escalators is €2054 in total health care costs and €2889 in RA-related health care costs. CONCLUSIONS: After adjusting for patient, clinical and demographic characteristics, the choice of risk adjustment method affected the results. In this study, the cost burden is higher for switchers when using the instrumental variable method as the risk adjustment technique.

OBJECTIVES: To assess the relationship between intent to persist (ITP) and reported compliance (RC) with osteoporosis treatment and to identify factors that predict persistence. METHODS: An online survey was conducted in November 2010 to 2011 with 500 MediGuard.com community members taking at least one osteoporosis medication. Survey items included the Treatment Satisfaction Questionnaire for Medication (TSQM) with 14 items across 4 domains (effectiveness, side effects, satisfaction, and convenience), the last observation carried forward (LOCF) method as the risk adjustment technique. Depending on the setup, the EF method is used to recognize the efficacy of highly innovative but expensive drugs for a specific patient subgroup. In the case of missing conventional alternatives, the EF yields no global measure of efficiency for comparisons across indications. Therefore, complementary methods like IQWiG’s budget impact analysis are recommended.